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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/006,796	12/04/2001	Eija Pirhonen	01942-00007	9843
22910	7590	09/26/2007		
BANNER & WITCOFF, LTD. 28 STATE STREET 28th FLOOR BOSTON, MA 02109-9601			EXAMINER YOUNG, MICAH PAUL	
			ART UNIT 1618	PAPER NUMBER
			MAIL DATE 09/26/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/006,796	Applicant(s) PIRHONEN ET AL.	
	Examiner Micah-Paul Young	Art Unit 1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 June 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-13 and 15-17 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-13 and 15-17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 6/21/07 has been entered.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1-13 and 15-17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

4. The claims are confusing because they recite a biodegradable implant comprising a rigid polymer matrix that comprises a plasticizer, however the claim further recites that the implant has a porous surface created by the plasticizer disbursed in the matrix. It is unclear what applicant is claiming. The claims are drawn to both an implant comprising a matrix with a plasticizer dispersed in the matrix and an implant with a porous surface and nonporous core. These are separate and discreet invention that cannot exist simultaneously since the plasticizer forms the pores, creating them as it exits the implant into the surrounding implanted tissue. The resulting implant has no plasticizer, a porous surface, nonporous core and higher bending

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resistance. The implant with the plasticizer is nonporous throughout, including the surface and has a low bending resistance. These implants are separate and distinct comprising different components and physical properties. It is the position of the Examiner that the claims are drawn to two separate and distinct inventions. As such the claims will be interpreted as an implant comprising a plasticizer. Clarification of this matter is required.

5. The terms "flexible and rigid" in claims 1,2,9 and 10 are relative terms which renders the claim indefinite. The terms "flexible and rigid" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. These terms are used to refer to the stiffness of the implant material however without a value for the elastic modulus, or bending resistance they are merely relative terms with no way of determining their significance. Gold is more rigid than a gel, yet less rigid than titanium. There is no clear distinction in the claims to determine how flexible and/or rigid an implant would need to be in order to meet the limitations of the claims. Correction is required.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

7. Claims 1-13, and 15-17 are rejected under 35 U.S.C. 102(e) as being anticipated by Niederauer et al (USPN 6,344,496 hereafter '496). The claims are drawn to an implant comprising a biodegradable polymer matrix, a drug and a plasticizer such as N-methyl-2-pyrrolidone. The claims are to a method of making the implant comprising forming a biodegradable implant and adding a plasticizer to the formed implant.

8. The '496 patent teaches a biodegradable implant material used for guiding tissue regeneration, comprising a biodegradable copolymer such as PLA/PGA and active agents such as growth factors enzymes and antibiotics (col. 8, lin. 23-48; examples). The implant is formed into films or strips that are cured and solidified. The films are next soaked in a plasticizer such as N-methyl-2-pyrrolidone (col. 9, lin. 45-50). The implant stiffens once the plasticizer is removed by co-solvent, either from the body during implantation or beforehand (*Ibid*). Bioactive Bioglass is added to the implant as an active agent and can be added before, during and after the solvent precipitation step (example 4). The solid rigid implant is used as cartilage replacements, tissue scaffolds or osteochondral implants (col. 6, lin. 48-59). These disclosures render the claims anticipated.

Response to Arguments

9. Applicant's arguments with respect to claims 1-13 and 5-17 have been considered but are moot in view of the new ground(s) of rejection.

Correspondence


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Micah-Paul Young whose telephone number is 571-272-0608. The examiner can normally be reached on M-F 6:00-3:30 every other Monday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


MP Young

Micah-Paul Young
Examiner
Art Unit 1618


MICHAEL G. HARTLEY
SUPERVISORY PATENT EXAMINER